IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 03-209-JJF (Consolidated)
RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

Rudolf E. Hutz, Esquire, Jeffrey B. Bove, Esquire, Collins J. Seitz, Jr., Esquire and Mary W. Bourke, Esquire of CONNOLY BOVE LODGE & HUTZ LLP, Wilmington, Delaware
Attorneys for Plaintiffs.

Steven J. Balick, Esquire and John G. Day, Esquire of ASHBY & GEDDES, Wilmington, Delaware.
Of Counsel: Darrell L. Olson, Esquire, John P. Giezentanner, Esquire, Douglas G. Muehlhauser, Esquire, William R. Zimmerman, Esquire, Payson LeMeilleur, Esquire, Sheila N. Swaroop, Esquire, Darryl H. Steensma, Esquire and Walter S. Wu, Esquire of KNOBBE, MARTENS, OLSON & BEAR, LLP, Irvine, California.
Jay R. Deshmukh, Esquire and George E. Heibel, Esquire of RANBAXY, INC., Princeton, New Jersey.
Attorneys for Defendants.

MEMORANDUM OPINION

December 16, 2005
Wilmington, Delaware

Farnan, District Judge.

This action was brought by Plaintiffs, Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Ltd. (collectively, "Pfizer") against Defendants, Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively, "Ranbaxy") for infringement of U.S. Patent No. 4,681,893 (the "'893 patent") and U.S. Patent No. 5,273,995 (the "'995 patent"). The '893 and '995 patents pertain to an atorvastatin calcium pharmaceutical composition sold by Pfizer under the registered name Lipitor®. Lipitor® is prescribed by doctors for the treatment of elevated cholesterol and is the largest selling pharmaceutical in history. This lawsuit arises in connection with Abbreviated New Drug Application ("ANDA") No. 76-477 filed by Ranbaxy seeking to commercially manufacture, use and sell a drug product containing atorvastatin calcium as its active agent. Pfizer filed four Complaints against Ranbaxy alleging that Ranbaxy's proposed ANDA product infringes the '893 and '995 patents under 35 U.S.C. § 271(e)(2). These Complaints have been consolidated into this action. By its Complaints, Pfizer has asserted two patents against Ranbaxy, the '893 patent and the '995 patent. Specifically, Pfizer alleges infringement of claims 1-4, 8 and 9 of the '893 patent and claim 6 of the '995 patent.

In response to Pfizer's Complaints, Ranbaxy filed an Answer and several Counterclaims. Ranbaxy alleges that it does not infringe either the '893 or '995 patents. Ranbaxy also challenges the validity of the patent term extension granted by the PTO for the '893 patent. With regard to the '995 patent, Ranbaxy contends that the asserted claim of the '995 patent, claim 6, is invalid for double patenting, obviousness and anticipation. Ranbaxy also contends that the '995 patent is unenforceable as a result of inequitable conduct by Warner-Lambert Company before the PTO.

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338, because this action arises under the patent laws of the United States. The Court also has subject matter jurisdiction over Ranbaxy's counterclaims pursuant to 28 U.S.C. §§ 1338, 2201 and 2202. The parties have submitted to the personal jurisdiction of the Court, and venue in this District is appropriate pursuant to 28 U.S.C. §§ 1391 and 1400.

The Court conducted a bench trial on the issues presented by the parties.[1] This Memorandum Opinion constitutes the Court's findings of fact and conclusions of law on the issues raised

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[1] The bench trial began on November 11, 2004 and was completed on December 13, 2004. Post-trial briefing was completed on April 4, 2005. In addition, two post-trial evidentiary motions (D.I. 314, 319) were filed by Pfizer, which will be addressed separately by the Court.

during trial.

BACKGROUND

I. The Parties

Pfizer Inc. is a Delaware corporation having a place of business in Morris Plains, New Jersey and corporate offices in New York City. Warner-Lambert Company was a Delaware corporation that became a wholly-owned subsidiary of Pfizer Inc. on June 19, 2000. Warner-Lambert Company was then converted into Warner-Lambert Company, LLC, a Delaware limited liability company. Warner-Lambert Export, Ltd. is a corporation formerly organized under the laws of Ireland with a registered office located in Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a partnership between C.P. Pharmaceuticals International, C.V., a limited partnership under the laws of the Netherlands, and Pfizer Overseas Pharmaceuticals, a private limited company incorporated in Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned subsidiary of Pfizer Inc. with registered offices in Dublin, Ireland. Through Parke-Davis Pharmaceuticals Research, a division of Warner-Lambert Company, Pfizer holds an approved New Drug Application for the atorvastatin calcium pharmaceutical composition sold under the name Lipitor®.

Ranbaxy Pharmaceuticals Incorporated is a Delaware corporation with a place of business located in Princeton, New Jersey. Ranbaxy Laboratories Limited is a corporation of India

with corporate offices located in New Delhi, India. Ranbaxy Pharmaceuticals Incorporated is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

II. The Patents Generally

A. The '893 Patent

The '893 patent is entitled "Trans-6-[2-(3- OR 4-carboxamido-substituted pyrrol-1-yl)alkyl]-4-hydroxypyran-2-one inhibitors of cholesterol synthesis." The inventor of the '893 patent is Dr. Bruce D. Roth. Pfizer has identified to the Food and Drug Administration that the '893 patent covers the atorvastatin calcium composition sold by Pfizer since 1997 under the name Lipitor®. The '893 patent was to expire on May 30, 2006; however, the PTO granted an extension pursuant to 35 U.S.C. § 156, extending the expiration date of the '893 patent to September 24, 2009, excluding a six month pediatric extension.

B. The '995 Patent

The '995 patent is entitled "[R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl-3-phenyl-4-[(phenylamino) carbonyl]-1H-pyrrole-1-heptanoic acid, its lactone form and salts thereof." Dr. Bruce D. Roth is also the inventor of the '995 patent. The compound covered by the '995 patent is commonly referred to as atorvastatin calcium. The '995 patent expires on December 28, 2010.

DISCUSSION

I. Claim Construction Of The '893 And '995 Patents

A. The Legal Principles Of Claim Construction

Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 388-90 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Markman, 52 F.3d at 979. In Phillips v. AWH Corp., 415 F.3d 1303, 1312-1317 (Fed. Cir. 2005), the Federal Circuit reaffirmed the claim construction principles set forth in Markman and reemphasized that the specification is the single best source for discerning the meaning of a claim.

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 318-319; Markman, 52 F.3d at 979-80 (citations omitted). However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 318-319 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered

in the context of intrinsic evidence").

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). If the patent inventor clearly supplies a different meaning; however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in the patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 & n.* (Fed. Cir. 1984) (citations omitted).

B. Scientific Background/Terminology Needed For Claim Construction

The parties' claim construction disputes impact the field of stereochemistry, a subfield of chemistry. Stereochemistry is concerned with the three-dimensional structure of organic molecules in space. An isomer is one of several molecular entities that have the same atomic composition or molecular formula, but a different stereochemical formula, meaning the atoms are the same in number and type but different in their spatial arrangement. Stereoisomers are compounds that have the same atoms and the same connection pattern of atoms or groups of atoms, but are different in the way that those atoms or groups of

atoms are arranged in space. Enantiomers are stereoisomers that are non-superimposable mirror images of each other. Enantiomers have identical physical properties, including solubilities and melting points, with the exception of their interactions with chiral matter and plane-polarized light. A racemate, or racemic mixture, is an equal mixture of two enantiomers, such that it contains 50% of one enantiomer and 50% of its opposite enantiomer. Racemates and enantiomers are distinct compounds, and in general, have different physical properties such as solubility and melting points.

Optical activity is a compound's ability to rotate plane-polarized light. A pure enantiomer rotates plane-polarized light in only one direction to the maximal amount permitted by that molecule. An unequal mixture of two opposite enantiomers is optically active and the degree of optical rotation reflects the percentage of each enantiomer present in the mixture. In a racemate, which is an equal mixture of two opposite enantiomers, the compound is not optically active, because the optical rotations of the enantiomers cancel each other out.

Chemists name and describe racemates and enantiomers with certain symbols and designations. In a molecule containing one asymmetric center, one enantiomer is designated as the R-enantiomer and its opposite is the S-enantiomer. A racemate is designated as an "RS" structure, because it contains equal

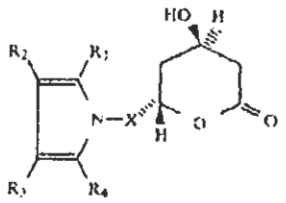
amounts of R and S enantiomers. A pure enantiomer is optically active because it rotates plane-polarized light either clockwise or counterclockwise. Chemists use a "+" symbol for the clockwise direction and a "-" symbol for the counterclockwise direction. A racemate is not optically active, and thus, chemists use the "±" to indicate a racemate.

The term "trans" is used to define the relationship of two groups to one another and indicates that two substituents are on opposite sides of a plane in a chemical structure. The term "cis" indicates that the two substituents are on the same side of the plane. Thus, the terms "cis" and "trans" describe relative stereochemistry.

Typically, when compounds are made synthetically in a lab, they are made as racemates. The process of isolating the enantiomers from a racemate is known as resolution.

C. The Claim Construction Of The '893 Patent

Pfizer asserts Claims 1-4, 8 and 9 of the '893 patent against Ranbaxy's ANDA product. Claim 1 is the only independent claim of the '893 patent and recites a compound of structural formula I drawn as:



I

This compound has a backbone of two rings joined by a bridge, designated as "X." The five-membered ring on the left contains a nitrogen atom designated as "N" and is a "pyrrole" ring. The six-membered ring on the right contains an oxygen atom ("O") and is a "pyran" or "lactone" ring. The left-hand ring has four possible substituents designated R_1 through R_4. Claim one of the patent designates the possible substituents for each of R_1, R_2, R_3, and R_4. The patent also designates the particular groups for X.

The parties' only claim construction dispute with respect to the '893 patent is what structural formula I represents. Ranbaxy contends that structural formula I represents only a genus of racemates. Pfizer agrees that claim 1 represents racemates, but contends that it is not limited to racemates. Pfizer contends that claim 1 also represents R-trans enantiomers, S-trans enantiomers and unequal mixtures of R-trans and S-trans enantiomers. The parties agree that structural formula I depicts an enantiomer; however, the parties also agree that this is not the meaning of structural formula I and that the meaning of structural formula I must be determined by reference to the context of the '893 patent.

After considering the claim language, the specification and the prosecution history of the '893 patent, the Court concludes that the '893 patent is not limited to racemates and embraces the two individual trans-form isomers, the R-trans and S-trans, as

well as their transform mixtures, including racemates. The Title, Abstract and Background sections of the '893 patent describe the invention as "trans" compounds. The Summary of the Invention then describes "certain trans" compounds and then defines the "broadest aspect of the present invention" as "compounds of structural formula I." DTX-13, col. 2, l. 2. In the Detailed Description section, the specification goes on to describe the "compounds of the present invention" as a "class of trans . . . " compounds. Id. at col. 3, l. 36-37. The patent expressly states:

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran 2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above.

Id. at col. 3, l. 45-54 (emphasis added). The Court understands this language to contemplate all trans-form compounds, including the individual R-trans isomer. In reaching this conclusion, the Court observes that the terms "racemate" or "racemic mixture" do not appear anywhere in the '893 patent, and there are no words of

limitation or chemical symbols used in claim 1 to restrict the meaning of "trans" or "trans-form" to the trans-racemate form.[2]

In contrast to claim 1, dependent claim 5 of the '893 patent uses the designation "Trans-(±)" to designate a racemic mixture. Ranbaxy contends that the use of this terminology should not be dispositive, because the patent identifies racemates in its examples without using the "±" designation. However, it is well-established that a claim is not limited by its examples or embodiments, unless the intrinsic evidence suggests an intent to so limit the claim. See e.g. Leibel Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004); Home Diagnostics, Inc. v. Lifescan, Inc., 381 F.3d 1352, 1357 (Fed. Cir. 2004) ("[T]he applicant's choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments."). As discussed by the Court in more detail below, the express language of the patent indicates no intention to limit the claims to the compounds exemplified. Further, that the "±" designation was used in the express language of claim 5 and not in the language of the other claims suggests to the Court

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[2] The expert witnesses of both Pfizer and Ranbaxy agree that the term "trans" refers to two groups on opposite sides of the plane. The term does not denote any specific three dimensional configuration such as only R-trans, only S-trans, or only a 50/50 mixture or racemate. (Clive Tr. 1553:5-1554:9; Roush Tr. 884:7-23). Further, both experts also agree that each of the individual R-trans and S-trans isomers, along with all mixtures of those isomers are in the "trans-form." (Clive Tr. 1572:12-1574:15; Roush Tr. 233:23-234:5, 882:2-883:24).

that the inventor knew how to limit a claim to a racemate, but chose not to so restrict the other claims of the patent. Liebel-Flarsheim, 358 F.3d at 910 ("The presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.") (citations omitted); Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1119 (Fed. Cir. 2004) (recognizing that "when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms"). In the Court's view, a contrary conclusion would make the "±" term in claim 5 surplusage. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed. Cir. 1996)

Ranbaxy contends that "by common convention, a racemate can be represented by depicting one of its constituent enantiomers." (D.I. 292 at 4) (emphasis added). Ranbaxy is correct that a depiction of an enantiomer can sometimes include or specify a racemate, but Ranbaxy has not demonstrated that, to one skilled in the art, such a depiction always or even usually specifies a racemate. Further, the fact that external sources may use an enantiomer to indicate a racemate does not overcome the intrinsic evidence of the '893 patent that the claimed invention is not limited to racemates. Phillips, 415 F.3d at 1319 (recognizing, to the extent extrinsic evidence is used in claim construction,

it must be considered in the context of the intrinsic evidence to be reliable).

Ranbaxy also seeks to limit the claimed invention to racemates because the reaction sequences and examples of the '893 patent are racemic. As the Court has concluded, however, the '893 patent is not limited to its examples and provides no indication that it should be so limited. For example, Table 1 of the patent reports results for test procedures used to determine the biological activity of examples of formula 1. However, the patent expressly identifies the Table 1 examples as "representative examples." Similarly, the '893 patent presents four working examples which also produce racemic mixtures; however, the patent states that these four examples "illustrate particular methods for preparing compounds in accordance with this invention. These examples are illustrative and are not to be read as limiting the scope of the invention . . ." DTX-13, col. 10, ll. 33-38 (emphasis added). Because the patent expressly evidences an intention that these examples be illustrative and the law disfavors limiting the patent based on its examples, the Court concludes that the reaction sequences and examples contained in the '893 patent do not limit the claimed invention to a racemic mixture or racemate.

Ranbaxy contends that if the Court accepts Pfizer's construction of the '893 patent, the patent is invalid for lack

of written description, because the patent does not disclose any methods for making enantiomers. In Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), the Federal Circuit recognized that "in claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass." However, the Federal Circuit also acknowledged in Lilly its holding in Utter v. Hiraga, 845 F.2d 993, 998-999 (Fed. Cir. 1988), that "[a] specification may, within the meaning of § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." While the Federal Circuit declined to extend Utter in Lilly to claims involving genetic material, it did not abandon its holding for chemical materials noting that in the case of generic formulae, "[o]ne skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." Lilly, 119 F.3d at 1568. In this case, the written description of the '893 patent is a generic formula which the patent specification expressly indicates includes all trans-enantiomers. Ranbaxy acknowledges that one skilled in the art would know how to resolve racemates into their constituent enantiomers, and therefore, the Court concludes that the generic formula description contained in the

'893 patent is sufficient to satisfy the written description requirement, regardless of whether the specific isomeric compounds are individually described in the patent.

Ranbaxy also contends that Warner-Lambert's representations during the prosecution of foreign counterparts to the '893 patent demonstrate that the '893 patent is limited to racemates. During the prosecution of the foreign counterparts to the '893 patent in Denmark and Europe, Warner-Lambert represented that the term "trans-" referred to "trans(±)." However, the Federal Circuit has recognized that "'the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate' for consideration in a claim construction analysis of a United States counterpart." TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C., 375 F.3d 1126, 1136 (Fed. Cir. 2004) (citations omitted). In the circumstances presented here, the Court finds that Warner-Lambert amended the Danish claims to limit them to racemates in response to the legal and procedural requirements specified by Danish law. Specifically, the Danish examiner found that under Danish law the scope of the claims was "too comprehensive." DTX 241 at P0279442. With respect to the European counterpart, Warner-Lambert made no actual amendments to the claims or specifications, but offered the "trans(±)" designation in response to the examiner's concerns that the

chemical nomenclature used in the patents was insufficiently articulated under European laws. The United States PTO raised no such concerns during the prosecution of the '893 patent, and Ranbaxy has not demonstrated to the Court any similarities between the foreign laws and the laws of the United States that would lead the Court to conclude that these changes and/or interpretations were not made in response to the unique aspects of the respective foreign laws under which patentability of the '893 counterparts was sought. Accordingly, the Court is not persuaded that Warner-Lambert's statements during the prosecution of foreign counterparts of the '893 patent are relevant to the Court's construction of the '893 patent issued in the United States.

In a similar vein, Ranbaxy contends that Pfizer is precluded from pursuing its proposed claim construction of the '893 patent based on statements made by Warner-Lambert during the prosecution of the '995 patent. However, the Federal Circuit has repeatedly held that arguments from a later, unrelated patent prosecution cannot be used to interpret and/or limit an earlier, unrelated and already issued patent.[3] Integra Lifesciences 1, Ltd. v. Merck KGaA, 331 F.3d 860, 868 (Fed. Cir. 2003), cert. granted on other grounds, 125 S. Ct. 823 (2005). Ranbaxy proffers a similar

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[3] See also Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1099-1100, 1104-1105 (Fed. Cir. 2002); Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 885, 862 n. 16 (Fed. Cir. 1988)

argument under the doctrine of judicial estoppel, but the Court is not persuaded that the principles of judicial estoppel are applicable in this context. Ranbaxy has offered no case law applying the doctrine of judicial estoppel in the context of claim construction, and in the Court's view, application of judicial estoppel in such a context would essentially undercut the Federal Circuit's clear pronouncements in the Integra line of cases.

In the alternative, even if the Court were to consider the doctrine of judicial estoppel, the Court concludes that Ranbaxy has not demonstrated its applicability. Whether judicial estoppel applies is determined by regional circuit law. In the Third Circuit, the party asserting the doctrine of judicial estoppel must establish that: "(1) the party to be estopped is asserting a position that is irreconcilably inconsistent with one he or she asserted in a prior proceeding; (2) the party changed his or her position in bad faith, i.e. in a culpable manner threatening to the Court's authority or integrity; and (3) the use of judicial estoppel is tailored to address the affront to the Court's authority or integrity." Montrose Med. Group Participating Sav. Plan v. Bulger, 243 F.3d 773, 777-778 (3d Cir. 2001). Ranbaxy contends that Pfizer's position in this case is irreconcilably inconsistent with its position during the prosecution of the '995 patent. Although there may be a degree

of tension between the positions taken by Pfizer in each instance, the Court cannot conclude that those positions are irreconcilably inconsistent. The arguments Pfizer made in the '995 prosecution were directed to the issue of whether the '995 patent claims were anticipated in light of the '893 patent, an analysis which is different from the infringement analysis. Further, the Court is not persuaded that Pfizer's positions demonstrate bad faith or that the use of judicial estoppel is necessary to address an affront to the Court's authority or integrity.

In sum, the Court concludes that its construction of the '893 patent is supported by the specification and the express language of the claims. In contrast, Ranbaxy's proffered construction is primarily based on extrinsic evidence, which is irrelevant to claim construction and inconsistent with the intrinsic evidence of the '893 patent. Accordingly, the Court reads structural formula I of the '893 patent to embrace all trans-form isomers, including enantiomeric atorvastatin calcium.

D. Claim Construction Of The '995 Patent

Pfizer asserts claim 6 of the '995 patent against Ranbaxy's ANDA product. Claim 6 is a dependent claim, which depends on claim 2, which in turn depends on claim 1. Claim 1 is the only independent claim of the '995 patent. The relevant claims provide:

1. [R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N, 4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; or pharmaceutically acceptable salts thereof.

2. A compound of claim 1 which is [R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid.

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6. The hemicalcium salt of the compound of claim 2.

DTX-35, col. 16, l. 60 - col. 17, l. 12 (emphasis added).

The parties' claim construction dispute regarding claim 6 is whether claim 6 can be construed to cover the salt atorvastatin calcium. Ranbaxy contends that claim 6 cannot be construed to cover the salt, because claim 6 depends on claim 2 and claim 2 narrows the subject matter of claim 1 from atorvastatin acid or atorvastatin lactone, or pharmaceutically acceptable salts thereof to the single compound, atorvastatin acid. Ranbaxy argues that because claim 2 does not encompass salts, dependent claim 6 cannot cover the salt atorvastatin calcium. According to Ranbaxy, a reading of claim 6 to include the salt would render the patent invalid under Section 112, paragraph 4.

In response, Pfizer contends that Ranbaxy's claim construction is erroneous, because Ranbaxy incorrectly assumes that claim 6, a dependent claim, must incorporate all of the limitations of claim 2, from which it depends regardless of the

actual language of claim 6. Because claim 6 expressly claims the hemicalcium salt of the compound of claim 2, Pfizer contends that claim 6 is properly construed to encompass the salt atorvastatin calcium.

The Court finds the language of claim 6 to be unambiguous to the extent that claim 6 is meant to claim the salt, atrovastatin calcium. The Court's conclusion is consistent with the express language of the claim and the understanding of the claim language to one skilled in the art. Claim 6 recites "[t]he hemicalcium salt of the compound of claim 2." Claim 2, on which claim 6 depends, defines atorvastatin acid. Thus, claim 6 effectively reads, "[t]he hemicalcium salt of atorvastatin acid." As a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form. Roush Tr. 910:3-912:4, 914:7-18. The specification of the '995 patent and claim 6 of the '995 patent comport with this standard practice by reciting the full name of the parent acid and then separately identifying the salt-forming ion. DTX-35, col. 4, ll. 3-6; Roush Tr. 914:7-18; Clive Tr. 1510:1-1517:2. Indeed, Ranbaxy utilizes this standard nomenclature in its ANDA application, as well. PTX-1011A at RA011211. Moreover, Ranbaxy's expert, Dr. Clive, had no difficulty understanding the

language of claim 6 as referring to atorvastatin calcium. Clive Tr. 1507:7-1508:2; 1508:14-1509:24.

Despite this standard use of chemical nomenclature and the fact that the meaning of claim 6 is clear to those skilled in the art, Ranbaxy contends that the Court should not interpret claim 6 to refer to atorvastatin calcium, because such an interpretation would render the claim invalid for failure to adhere to the drafting requirements for dependent claims set forth in Section 112. Pursuant to Section 112, paragraph 4, "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Ranbaxy contends that there is a technical problem in the drafting of claim 6, because claim 1, from which claim 6 and claim 2 depend, recites three separate compositions: (1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts of these two compounds. Claim 1 differentiates among these three compositions using the disjunctive "or." As a dependent claim, claim 2 narrows the subject matter of claim 1 from atorvastatin acid; or atorvastin lactone; or pharmaceutically acceptable salts thereof, to the single compound atorvastatin acid. If claim 2 is limited to atorvastatin acid and it excludes the limitation from claim 1 referring to "pharmaceutically acceptable salts thereof," then

Ranbaxy argues that claim 6 cannot be read to encompass that which it expressly names, the hemicalcium salt of atorvastatin.

While the Court recognizes that there may be a technical problem in the drafting of claim 6, the question presented to the Court is whether this drafting problem is sufficient to render the claim invalid if the claim is read consistently with its meaning to those skilled in the art. To reach this conclusion, the Court would be required to declare an issued claim invalid because of the failure to adhere to the drafting technicalities for dependent claims under Section 112, paragraph 4.[4] The Court has been unable to locate any precedent applying Section 112, paragraph 4 to invalidate a patent[5], and based on the legislative

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[4] The Court is not persuaded that claim 6 can be read in any other manner, and Ranbaxy has not offered a plausible alternative reading for claim 6. Because the Court cannot construe the claim in any other manner, the question for the Court is whether claim 6 is invalid. See Phillips v. AWH Corp., 415 F.3d 1303, 1328 (Fed. Cir. 2005) (reaffirming the principle that construing claims so as to maintain their validity is only applicable when the claim language is ambiguous and recognizing that claims cannot be construed differently from their plain meaning to uphold their validity); Nazomi Communications, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368-1371 (Fed. Cir. 2005) (stating that "courts should not rewrite claims to preserve validity"); Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) (recognizing that if "the only claim construction that is consistent with the claim's language and the written description renders the claim invalid," then "the claim is simply invalid").

[5] In arguing that Section 112, paragraph 4 should be considered an invalidating provision, Ranbaxy refers the Court to cases that applied Section 112, paragraph 1 to invalidate a patent for lack of written description and enablement and Section 112, paragraph 2 to invalidate a patent for indefiniteness. Ranbaxy contends that paragraph 4 should not be treated

history of Section 112, paragraph 4, the Court understands the provision to be limited to matters of form, rather than matters of substance. Legislative history concerning this statutory section suggests that its provisions were meant to increase the fees payable to the Patent Office and expedite the prosecution of patent applications to make new technology available to the public more quickly. See S. Rep. No. 89-301 (1965), reprinted in 1965 U.S.C.C.A.N. 2315, 2319-2323. There is no indication in this legislative history that paragraph 4 was intended to be an invalidating provision. The Manual of Patent Examining Procedure ("MPEP") takes an approach consistent with the legislative history by viewing the failure to comply with paragraph 4 as a matter to be addressed through an objection to the claim and not

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differently from paragraphs 1 and 2 of Section 112. The Court understands that the Federal Circuit has applied Section 112, paragraph 1 to invalidate a claim; however, the Court also understands that even this limited use of Section 112, paragraph 1 has not been embraced by all members of the Court. For example, there is significant disagreement over whether "written description" should be divorced from "enablement" and considered a separate and independent ground for invalidity. See e.g. University of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1307-1314 (Fed. Cir. 2004) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976-987 (Fed. Cir. 2002) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.). In light of this split among the Circuit judges, the Court is not persuaded that a further extension of invalidity principles to paragraph 4 should be made by this Court.

a rejection of the claim's patentability under 35 U.S.C. § 112, 4.[6] Because the PTO considers improper dependent claims in this manner, the Court is not persuaded that the law of invalidity should be extended to reach Section 112, paragraph 4. Thus, the Court concludes that Section 112, paragraph 4 should not be used to invalidate an issued patent claim.[7] See 35 U.S.C. § 282 (recognizing that issued patent has statutory presumption of validity); Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 960 (Fed. Cir. 1997) ("Procedural lapses during examination, should they occur, do not provide grounds of invalidity. Absent proof

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[6] MPEP 608.01(n) provides:

> Where a claim in dependent form is not considered to be a proper dependent claim under 37 C.F.R. 1.75(c), the examiner should object to such claim under 37 C.F.R. 1.75(c) and require cancellation of such improper dependent claim or rewriting of such improper dependent claim in independent form. See Ex parte Porter, 25 U.S.P.Q.2d 1144, 1147 (Bd. of Pat. App. & Inter. 1992) (A claim determined to be an improper dependent claim should be treated as a formal matter, in that the claim should be objected to and applicant should be required to cancel the claim (or replace the improper dependent claim with an independent claim) rather than treated by a rejection of the claim under 35 U.S.C. Section 112, fourth paragraph.). The applicant may thereupon amend the claims to place them in proper dependent form, or may redraft them as independent claims, upon payment of any necessary additional fee.

MPEP § 608.01(n) at 600-80 (8th ed. rev. 2, May 2004).

[7] The Court further notes that the PTO raised no objections to the format or dependency of claim 6 or any of the other, similarly-worded claims to atovastatin salts, all of which depend on claim 2. DTX 139 at RA014772-74, RA014784, RA0147804-806, RA014813-14, RA014828-833.

of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.").

In sum, the Court interprets claim 6 of the patent to mean the salt of atorvastatin calcium. The Court's claim construction is consistent with the express language of the claim and the understanding of the claim to those skilled in the art. To the extent that the Court's claim construction conflicts with the requirements for dependent claims set forth in Section 112, paragraph 4, the Court concludes that this statutory provision provides no basis to invalidate a claim.

II. Infringement Of The '893 And '995 Patents

A. Applicable Legal Principles

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States during the term of the patent...." 35 U.S.C. § 271(a). A patent owner may prove infringement under either of two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987); Robert L. Harmon, Patents and the Federal Circuit 195 & n. 31 (3d ed.1994). In determining whether a patent has been literally infringed, the patent owner has the

burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

Infringement is a two step inquiry. Step one requires a court to construe the disputed terms of the patent at issue. Step two requires a court to compare the accused products with the properly construed claims of the patent. Having resolved the claim construction disputes regarding the '893 and '995 patents, the Court will proceed to a comparison between Ranbaxy's accused ANDA product and the claims of the '893 and '995 patents as construed by the Court.

B. Whether Pfizer Has Established By A Preponderance Of The Evidence That Ranbaxy's ANDA Product Literally Infringes The '893 Patent

The parties have stipulated that Ranbaxy's ANDA product contains the enantiomer atorvastatin calcium. Because the '893 patent has been construed to embrace enantiomers in the trans-form and not just racemates, the Court concludes that Ranbaxy's ANDA product literally infringes claims 1-4 of the '893 patent. The Court also concludes that Ranbaxy is likely to market or sell a composition containing atorvastatin calcium as embraced by claim 8 of the '893 patent, for use in the method claimed by claim 9 of the '893 patent for inhibiting cholesterol biosynthesis in a patient in need of such treatment. Therefore,

the Court concludes that Ranbaxy literally infringes claims 8 and 9 of the '893 patent.

C. Whether Pfizer Has Established By A Preponderance Of The Evidence That Ranbaxy's ANDA Product Literally Infringes The '995 Patent

Ranbaxy has admitted that the active ingredient, atorvastatin calcium, in Ranbaxy's ANDA product is the hemicalcium salt of the R-[R*, R*]-enantiomer. Because Ranbaxy's ANDA and associated Drug Master File ("DMF") indicate that its product will contain atorvastatin calcium, the Court concludes that Ranbaxy literally infringes claim 6 of the '995 patent as that claim has been interpreted by the Court.

III. The Validity Of The '893 Patent Term Extension

A. Applicable Legal Principles

Under the Hatch-Waxman Act, a patentee can obtain an extension of the ordinary patent term if the patent claims an invention which is subject to a regulatory review period before its commercial marketing or use. 35 U.S.C. § 156. Section 156 applies to a "drug product," which is defined, in pertinent part, as "a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Act), . . . including any salt or ester of the active ingredient as a single entity or in combination with another active ingredient." 35 U.S.C. § 156(f)(1), (2).

In applying for a patent extension, the applicant has a duty of candor and good faith toward the PTO, which encompasses a duty to disclose "material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding . . . ." 37 C.F.R. § 1.765(a). Information is considered material "where there is a substantial likelihood that the [PTO] . . . would consider it important in determinations to be made in the patent term extension proceeding." Id.

The presumption of validity applies to the PTO's determination to grant a patent term extension. To overcome this presumption, the party challenging the extension must come forward with clear and convincing evidence that the extension is invalid. See Helfix Ltd. v. Blok-Lok Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000).

B. Whether Ranbaxy Has Established By Clear And Convincing Evidence That The Patent Term Extension Of The '893 Is Invalid

Ranbaxy contends that the patent term extension of the '893 patent is invalid. Specifically, Ranbaxy contends that (1) the '893 patent does not claim atorvastatin calcium as required by 35 U.S.C. § 156; and (2) Pfizer violated the duty of disclosure by knowingly withholding from the Director representations made by Warner-Lambert regarding the '893 patent during the prosecution of the '995 patent and its European counterparts.

Based on the Court's claim construction of the '893 patent, the Court concludes that Ranbaxy's first argument provides no basis for invalidating the patent term extension of the '893 patent. The Court has construed the '893 patent to embrace atorvastatin calcium, and Pfizer provided the PTO with evidence supporting its assertion that the active pharmaceutical agent in Lipitor® is atorvastatin calcium. The PTO agreed with Pfizer's construction and concluded that the active ingredient in Lipitor® fell within the scope of the '893 patent. The PTO's determination in this regard is entitled to deference. Merck & Co. v. Teva Pharms. U.S.A., Inc., 347 F.2d, 1367, 1373-1374 (Fed. Cir. 2003) (citing Glaxo Ops. UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990)).

Ranbaxy contends that this case is similar to the circumstances in Hoeschst-Roussel Pharmaceuticals, Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997).[8] In the Court's view, however, the circumstances in Hoeschst are distinguishable from the circumstances in this case. In Hoeschst, the Federal Circuit

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[8] Ranbaxy also relies on Hoeschst to argue that the '893 patent does not "claim" atorvastatin calcium, because Ranbaxy contends that the patent lacks a sufficient written description to claim this compound under 35 U.S.C. § 112. Ranbaxy is correct that the Federal Circuit in Hoeschst discussed the meaning of what a patent "claims" by reference to Section 112 for purposes of a patent term extension; however, the Court has previously concluded, in the context of its claim construction analysis, that the '893 patent is not invalid for lack of a written description.

invalidated a patent term extension on the grounds that the patent did not claim the product at issue. The patent in Hoeschst claimed the chemically distinct product 1-hydroxy-tacrine and the method of using that product. The patent did not claim the active ingredient of the product that received FDA approval, i.e. tacrine hydrochloride, or a method of using that ingredient. Rather, the active ingredient of the product at issue metabolized into the patented compound after it was ingested in the body. The Federal Circuit concluded that the active ingredient must be present in the drug product when administered for purposes of obtaining a valid patent term extension. Unlike Hoeschst, in this case, the '893 patent claims the active ingredient in Lipitor®, and therefore, the Court concludes that Hoeschst is inapposite.

Ranbaxy also contends that the patent term extension of the '893 patent is invalid based on Pfizer's alleged failure to disclose material information to the Director. In the context of its claim construction, the Court has concluded that the disclosures made by Warner-Lambert in connection with the prosecution of the '995 patent and foreign counterparts of the '893 patent are irrelevant to a determination of the scope of the claims of the '893 patent. Because this information is not relevant to the patent's scope, the Court concludes that Ranbaxy has not established that the allegedly withheld information is

material such that it was required to be disclosed during the application process for the patent term extension. Accordingly, the Court concludes that Ranbaxy has not established that the patent term extension of the '893 patent is invalid.

IV. The Validity Of The '995 Patent

A. Whether Claim 6 Of The '995 Patent Is Invalid For Non-Statutory Double Patenting Over Pfizer's '080 Patent

1. Applicable Legal Principles

The non-statutory, obvious-type double patenting analysis involves two steps: (1) the court must construe the claim in the earlier patent and the later patent and determine the differences between the two patents, and (2) the court must determine whether the differences in the subject matter between the two claims render the claims patentably distinct. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968 (Fed. Cir. 2000). In assessing the differences between the claims, the Court may not treat the earlier claim as prior art. Rather, specific attention must be given to what is claimed in the earlier patent. General Foods Corp. v. Studiengesellschaft Kohle, 972 F.2d 1272, 1278, 1280 (Fed. Cir. 1992) ("[I]t is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.")

(italics in original). If the later claim is anticipated by or obvious in light of the earlier claim, then the later claim is not patentably distinct from the earlier claim, and it is invalid for obvious-type double patenting. Barr, 251 F.3d at 968.

Non-statutory double patenting is a judicially created doctrine, the purpose of which is to preclude a patent owner "from obtaining an extension of the right to exclude others from practicing his invention through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." Id. at 967-968; see In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997). Unlike the obviousness inquiry under 35 U.S.C. § 103, non-statutory double patenting does not require an inquiry into the objective criteria of non-obviousness. Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377-1378 n.1 (Fed. Cir. 2003).[9] The party challenging validity on the basis of non-statutory double patenting bears the burden of establishing invalidity by clear and convincing evidence. Symbol Techs., Inc. v. Option, Inc., 935 F.2d 1569, 1580 (Fed. Cir. 1991) (describing burden of proof for non-statutory double patenting as "heavy and unshifting").

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[9] Pfizer contends that, notwithstanding Judge Rader's footnote in Geneva, it is appropriate to consider objective indicia of nonobviousness in the case of nonstatutory, obvious-type double patenting. To the extent such an analysis of these secondary considerations is required, the Court incorporates by reference its discussion of these factors in the obviousness analysis contained in Section IV.B.2 infra.